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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,028	06/22/2006	Nobuyuki Takakura	1254-0318PUS1	4443
2292 7590 11/15/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER KIM, TAEYOON				
ART UNIT 1651		PAPER NUMBER		
NOTIFICATION DATE 11/15/2010		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/584,028

**Applicant(s)**

TAKAKURA ET AL.

**Examiner**

Taeyoon Kim

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-16 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16, 18, 19, 25 and 26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment and response filed on 9/14/2010 has been received and entered into the case.

Claims 1-11, 17 and 27 are canceled, claims 20-24 have been withdrawn from consideration as being drawn to non-elected subject matter, and claims 12-16, 18, 19, 25 and 26 have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C. §112 has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §103 has been withdrawn due to the amendment.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-16, 18, 19, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly added limitation is directed to the step of culturing the bone marrow cells or cord blood-derived cells with the fat cells, fat precursor cells and somatic stem cells isolated from mammalian fat tissues.

While the specification discloses that the cells isolated from fat tissue include fat cells, fat precursor cells and somatic stem cells (p.6, lines 11-12). However, the specification also discloses that these cells are confirmed to be Lin-negative, c-Kit-negative to weak-positive, and  $\beta$ 1 integrin-positive cells (p.6, lines 13-14). According to the inventor's own publication (Yamada et al.

2006, IDS ref.),  $\beta 1$  integrin or CD29 is a marker for stem/progenitor cells in brown adipose tissue (BAT) derived cells (BATDCs) (p.663, left col.). Therefore, it appears that fat cells, fat precursor cells, and somatic stem cells, which are confirmed to be CD29 positive, are either stem or progenitor cells present in fat tissue. This is contradicting disclosure when "fat cells" are considered as differentiated adipocytes.

Thus, since there is no definition given in the specification to the term "fat cells", and the specification discloses that the "fat cells" are also CD29 positive, it is not clear whether the term "fat cells" intends to point out CD29 positive stem/progenitor cells.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-15, 18, 19, 25 and 26 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mesenchymal stem cells or hematopoietic stem cells present in bone marrow or cord blood, does not reasonably provide enablement for those terminally differentiated cells present in bone marrow or cord blood. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The instant claims are directed to any cell from bone marrow or cord blood would differentiate into myocardial precursor cells and/or myocardial cells in the presence of fat tissue derived cells.

While it is enabled for those stem/progenitor cells present in the bone marrow or cord blood, however, it is not enabled for the terminally differentiated cells or those which lost the ability to differentiate into myocardial lineage. It is well known in the art that bone marrow or

cord blood contains not only stem/progenitor cells but also cells already differentiated into a certain lineage (e.g. hematopoietic lineage) including leukocytes (mononuclear cells). Since these terminally differentiated cells are not capable of differentiating or trans-differentiating into myocardial cells, not all cells present in bone marrow or cord blood would be enabling the claimed invention.

It is understood that the claimed invention requires stem or progenitor cells present in bone marrow or cord blood. However, the claimed invention claims broadly that any cell present in bone marrow or cord blood would have such capacity to be differentiated into myocardial cells. However, there is no disclosure in the specification to provide enablement to encompass the entire scope of the claimed invention. Applicant is advised to incorporate the limitation of claim 16 to limit the bone marrow cells being either mesenchymal or hematopoietic stem cells.

With regard to the cord blood-derived being mononuclear cells, it is understood that not all mononuclear cells are capable of differentiating into myocardial cells. As discussed above, lymphocytes and/or leukocytes are mononuclear cells but they do not have the claimed capability to differentiate into myocardial cells. It is construed that mononuclear cell fractions obtainable from cord blood would contain stem and/or progenitor cells capable of differentiating into myocardial cells. Applicant is advised to amend the claims to limit that the cells being differentiated into myocardial precursor and/or myocardial cells are stem and/or progenitor cells without introducing any new matter to the current application.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/  
Primary Examiner, Art Unit 1651